Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? Swissmedic (CH), MoH (IT)
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2019-04-25
Reference number assigned by the manufacturer FSCA232
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report
Status of submitter (•) Manufacturer ( ) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name Aesculap AG	
Contact Name Thorsten Barthelmes	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone 07461 95-2212	**Fax** 07461 95-1555
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name Aesculap AG	
Name of the contact person Thorsten Barthelmes	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone 07461 95-2212	**Fax** 07461 95-1555
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

6 Medical device information

new

Class

- ○ AIMD Active implants
- ○ MDD Class III
- ◉ MDD Class IIb
- ○ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	57944

Nomenclature text

Endoscopic electrosur...

Commercial name/ brand name / make

CAIMAN MARYLAND NON ARTICULAT.D5/360MM

Model number	**Catalogue number**
PL770SU	
Serial number(s)	**Lot/batch number(s)**
	52481830
Device Mfr Date	**Expiry date**
2019-01-16	2021-01-15

Notified Body (NB) ID-number

CE0123

Accessories / associated devices (if applicable)

Semi-finished products which are involved:
PL770204 - DISSECTION CLIP - Defined for Caiman Maryland
PL720204 - DISSECTION CLIP - Defined for Caiman Blunt Jaw

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

The Caiman® Seal & Cut is a bipolar RF sealing system, which consists of the Lekrafuse® RF generator and Caiman® instruments. This system can be used for grasping, preparation, sealing and cutting of tissue during open and minimally invasive surgical procedures. Caiman® Seal & Cut can be used on vessels and vessel bundles with diameters up to and including 7 mm as well as soft tissue in general surgery and also surgical specialties such as gynecology, urology and bariatric, colorectal and thoracic surgery.

During the course of post-market surveillance, Aesculap AG received feedback that during an operation with a CAIMAN MARYLAND NON ARTICULAT.D5/360MM - PL770SU no acoustic warning signal was triggered despite the fact that the coagulation cycle was not successfully completed.

The complaint analysis revealed a deviation from the product specification that occurred during the production process of a specific batch (52481830). A non-compliant component has been installed in the jaw section of the device. Due to the resulting deviation from the specification, the jaw no longer closes flush. The failure could be limited to batch 52481830.

The investigation of a comparative instrument, the surgeon sent to AAG, showed that a wrong component was assembled in the instrument. Instead of the Dissection Clip that is defined for Caiman Maryland (PL770204) the Dissection Clip for Caiman Blunt Jaw (PL720204) was installed. The Dissection Clip is positioned at the back of the jaws. The Dissection Clips are delivered by the supplier in packages containing 1000 pieces. In the factory these packages are filled into boxes. There are different boxes used for each variant (Caiman Maryland and Caiman Blunt Jaw). Further investigation revealed that befor and after processing/ assembling the affected PL770SU with batch 52481830, Caiman Blunt Jaw batches were processed. To avoid a mix up there are different cupboards for each variant. The employee did not remove the box of the Dissection Clips between different batches. Therefore he built in the wrong clips, which result in a bigger gap in the jaw. The technical failure of a wrong Dissection Clip (defined for Blunt Jaw) built in the Maryland variant results in a potentially reduced sealing performance at the back of the jaw.

There are two potential scenarios the defective device could cause harm. This could be either intra- or post-operatively.

Intra-operative:
In the case the surgeon recognizes the insufficient coagulation during the operation he has the following options:
- Second coagulation with the same Caiman Maryland instrument
- Use another (new) Caiman Maryland instrument
- Use another sealing device (from competitor)
- Clipping the vessel with a Clip (DS Clip, Ligature Clip, etc.)
- Suture of the vessel

Post-operative:
In the worst case scenario the incomplete coagulation would not be detected intra-operatively. An insufficient coagulation may result in a post-operative bleeding.
If the post-operative bleeding is recognized in time, a revision surgery is necessary to stop the bleeding.

There are no special clinical factors that can mitigate the risk since the cause is a technical fault. The only factor that could mitigate the risk is the amount of tissue that has to be coagulated.The described risk applies equally to all patient populations. The health consequence has no public health impact beyond users.

The affected batch 52481830 included 60 devices which are package in 10 boxes.

The identification of an affected product can be clearly carried out via the label on the sterile blister (identification marks REF: PL770SU and LOT: 52481830).

Until the date of this report two complaints were received regarding the described error pattern for PL770SU with batch 52481830.

Description and justification of the action (corrective / preventive)

As a consequence all of the end customers who have received affected products will be notified and asked to return the available products immediately.

There were no available inventory stock of the affected batch.

A CAPA was initiated.

Advice on actions to be taken by the distributor and the user

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

We plan to conduct and complete the FSCA within the next 3 months.

Attached please find

☒ Field Safety Notice (FSN) in English

☐ FSN in national language

☐ Others (please specify)

Field Safety Notice (FSN) in German

FSN Status

○ Draft FSN

◉ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☐ AT	☐ BE	☐ BG	☒ CH	☐ CY	☐ CZ	☐ DE	☐ DK
☐ EE	☐ ES	☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☐ NL
☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI	☐ SK	☐ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature 25.04.19

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

423968
25. April 2019
Christian Strobel